DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Cossington Limited
% Diane Mandell Horwitz, Ph.D.
Mandell Horwitz Consultants, LLC
2995 Steven Martin Drive
Fairfax, Virginia 22031

March 5, 2015

Re: K143100
Trade/Device Name: NP Cements Genta / NP Cement System Genta
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: LOD, MBB
Dated: January 23, 2015
Received: January 23, 2015

Dear Dr. Horwitz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K143100

Device Name
NP Cements Genta / NP Cement System Genta

Indications for Use *(Describe)*
NP Cements Genta / NP Cement System Genta are intended for the fixation of prosthesis to living bone in the second stage of a two-stage revision for total joint arthroplasty after the initial infection has been cleared.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

1 GENERAL INFORMATION

1.1 Submitter and Owner of the 510(k)

Cossington Ltd
1 Princeton Mews
Kingston Upon Thames
Surrey KT2 6PT
United Kingdom

1.2 Official Correspondent

Diane Mandell Horwitz, PhD, RAC
Regulatory affairs Consultants
Mandell Horwitz Consultants, LLC
2995 Steven Martin Drive
Fairfax, Virginia 20031

Telephone: (703) 307-2921
Fax: (703) 242-1117
E-mail: dmh@mandellhorwitzconsulting.com

1.3 Devices Subject of this 510(k)

NP Cements Genta – Low and High Viscosity
NP Cements System Genta– Low and High Viscosity

1.4 Date of Preparation

October 16, 2014

2 NAME OF THE DEVICE AND CLASSIFICATION INFORMATION

This traditional 510(k) has been submitted for the following devices.

- NP Cements Genta – Low and High Viscosity
- NP Cements System Genta – Low and High Viscosity

2.1 Trade/Proprietary Name

As of the date of this application, the Sponsor has not yet developed a trade name for the new bone cements.

2.2 Common/Usual Name

PMMA bone cement with antibiotic for orthopedics
PMMA bone cement with antibiotic for orthopedics within a syringe-like device system

2.3 Classification Information

Classification Name: Polymethylmethacrylate (PMMA) Bone Cement

Classification Regulation: 21 CFR § 888.3027

Regulatory Class: Class II

Product Code: LOD – Bone Cement
MBB – Bone Cement, Antibiotics

Panel: Orthopedic

3 PREDICATE DEVICE

The predicate device is as follows:

- Tecres Cemex Genta HV, which was cleared originally through 510(k) application K033596 and then subsequently through 510(k) application K092773.

4 DEVICE DESCRIPTION

The NP Cements Genta and NP Cements System Genta are PMMA, radiopaque bone cements, containing gentamicin and color additives to impart a green color, designed for the fixation of prosthesis to the living bone. The devices contain the same individual chemical constituents, but are supplied in different ways:

1. NP Cements Genta are a traditional bone cement product. The liquid is contained in a vial and the powder in a sachet; these components are packaged in unitary blister with Tyvek lid, which is placed in an aluminum bag. The components are manually mixed immediately prior to use.

2. NP Cements System Genta stores the powder and liquid components separately within a closed syringe-like device that serve as both mixing chamber and extrusion device. The device is provided with a vacuum tube and a cannula with the pusher rod. The product is packaged in a double blister, the external blister is sealed with a Tyvek lid, and then placed in an aluminum bag.

The devices are sold disposable and sterile. The NP Cements Genta are available in a low and high viscosity version. The NP Cements System Genta are also available in a low and high viscosity version.

5 INDICATIONS FOR USE

Below is the indication for use for each bone cement.

NP Cements Genta/NP Cements System Genta are intended for the fixation of prosthesis to living bone in the second stage of a two-stage revision for total joint arthroplasty after the initial infection has been cleared.

6 COMPARISON OF THE INTENDED USE WITH THE PREDICATE DEVICE

The NP Cements Genta and the NP Cements System Genta have the same indication for use statements (other than the identification of the trade name) as the predicate device, and thus have the same intended use, as shown in Table 1.

Table 1: Comparison of the Indication Statement with the Predicate Device

Device	**Indication for Use**
Cossington NP Cement Genta / NP Cement System Genta	NP Cements Genta/NP Cements System Genta are intended for the fixation of prosthesis to living bone in the second stage of a two-stage revision for total joint arthroplasty after the initial infection has been cleared.
Tecres Cemex Genta HV (K033596 and K092773)	Cemex Genta HV is intended for the fixation of prosthesis to living bone in the second stage of a two-stage revision for total joint arthroplasty after the initial infection has been cleared.

7 COMPARISON OF THE TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The NP Cements Genta and NP Cements System Genta share many of the same technological characteristics compared to the predicate Cemex Genta HV, including important considerations such as the same materials, and mechanical and chemical-physical performances. There are, however, some differences in the shelf life, method of sterilization of the powder component, the presence of colored pigments and how the device is supplied to the surgeon for the system version. These comparisons are summarized in Table 2.

Table 2: Comparison of the Technological Characteristics with the Predicate Device

Characteristics	**Cossington NP Cements Genta NP Cements System Genta**	**Tecres Cemex Genta HV K033596 and K092773**	**Comparison**
Main Components	Polymethylmethacrylate (PMMA) Methylmethacrylate (MMA) Gentamicin Sulphate Barium Sulphate	Polymethylmethacrylate (PMMA) Methylmethacrylate (MMA) Gentamicin Sulphate Barium Sulphate	Same
Other Components	Benzoyl peroxide N,N-Dimethyl-p-toluidine Hydroquinone	Benzoyl peroxide N,N-Dimethyl-p-toluidine Hydroquinone	Same
Coloring Agents	Pigments	None	Different

Characteristics	**Cossington NP Cements Genta NP Cements System Genta**	**Tecres Cemex Genta HV K033596 and K092773**	**Comparison**
Mixing/Application	Manual Syringe-like device (System version)	Manual	Same for manual; different for system
Powder Sterilization Method	Gamma-ray irradiation (manual) Ethylene oxide (system)	Ethylene Oxide	Same for manual; different for system
Sterility Assurance Level (SAL) – Powder	10^{-6}	10^{-6}	Same
Liquid Sterilization Method	Filtration	Filtration	Same
SAL – Liquid	10^{-3}	10^{-3}	Same
Shelf Life	2 years	5 years	Different

8 PERFORMANCE DATA

This 510(k) submission provided performance data to establish the substantial equivalence of the new bone cements to the predicate bone cement. Performance testing was conducted in accordance with the "FDA Class II Special Controls Guidance Document: Polymethylmethacrylate (PMMA) Bone Cement; Guidance for Industry and FDA" dated July 17, 2002. The following is a summary of the performance data.

Sterilization and Shelf Life: The devices are sterilized using standard methods and the sterilization cycles have been validated following international standards. The shelf life of the devices has been established in ongoing stability studies.

Biocompatibility: Biocompatibility testing of the NP Cements Genta and NP Cements System Genta has been performed to show the device materials are safe, biocompatible and suitable for their intended use. Both ISO 10993 and FDA Draft Guidance "Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" have been taken into account to evaluate the biocompatibility of the device materials.

Performance Testing (Chemical, Material and Mechanical): Performance testing was performed to characterize the bone cements in accordance with special controls guidance document. This testing included the following:

- Mixing and application characteristics (e.g., dough time, setting time)
- Chemical composition (e.g., residuals, molecular weight and polymer structure, glass transition temperature)
- Thermal properties (e.g., polymerization temperature)
- Mechanical properties (e.g., modulus and flexural properties, static compression and bending, fatigue testing, fracture toughness and viscoelasticity)

The performance data demonstrate that the new devices are substantially equivalent to the predicate device, and meet the requirements of the Special Controls Guidance document.